

Food and Drug Administration, HHS

§ 558.95

Bacitracin zinc in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(ii) 4 to 50	Turkeys and pheasants: for increased rate of weight gain and improved feed efficiency.	Growing turkeys and pheasants	046573
(iii) 5 to 20	Quail; for increased rate of weight gain and improved feed efficiency.	Growing quail; feed as the Type C feed to starting quail through 5 weeks of age.	046573
(iv) 10 to 25	Laying chickens; improved feed efficiency and increased egg production.	046573
(v) 10 to 50	Swine; increased rate of weight gain and improved feed efficiency.	Growing and finishing swine	046573
(vi) 20	Growing-finishing swine; increased rate of weight gain.	In Type C feed	046573
(vii) 20 to 40	Growing-finishing swine; improved feed efficiency.do	046573

(2) It is used in feed for growing cattle at 35 to 70 milligrams per head per day as follows:

(i) To aid in stimulating growth and improving feed efficiency.

(ii) For increased rate of weight gain and improved feed efficiency; see sponsor 046573.

(3) It may be used as approved in combination with:

(i) Amprolium alone and with roxarsone as in § 558.55.

(ii) Amprolium and ethopabate alone and with roxarsone as in § 558.58.

(iii) Carbarsone as in § 558.120.

(iv) Clopidol alone and with roxarsone as in § 558.175.

(v) Decoquinat alone and with roxarsone as in § 558.195.

(vi) Hygromycin B alone and with penicillin as in § 558.274.

(vii) Lasalocid sodium alone or with roxarsone as in § 558.311.

(viii) Monensin alone and with roxarsone as in § 558.355.

(ix) Naracin as in § 558.363.

(x) Robenidine as in § 558.515.

(xi) Salinomycin alone and with roxarsone as in § 558.550.

(xii) Zoalene alone and with arsanilic acid or roxarsone as in § 558.680.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.78, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.95 Bambermycins.

(a) *Approvals.* To sponsors identified by drug labeler codes in § 510.600(c) of

this chapter for use of bambermycins Type A medicated articles as bambermycins activity per pound in paragraph (d) of this section as follows:

(1) To 057926: 2, 4, and 10 grams for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) To 057926: 0.4 gram for use as in paragraph (d)(2) of this section.

(3) To 011490: 0.4 and 2 grams for use as in paragraph (d)(2) of this section.

(4) To 016968, 017519, and 017790: 0.4 and 2 grams for use as in paragraph (d)(2) and 2 grams for use as in paragraph (d)(3) of this section.

(5) To 057926: 10 grams to make 40 to 800 grams per ton Type B feed for use as in paragraph (d)(4) of this section.

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) *Conditions of use*—(1) *Broiler chickens.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams

(.0125 percent) plus ethopabate, 36.3 grams (.004 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur. For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 36.3 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(iv) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 3.63 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(v) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved

feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(vi) *Amount per ton.* Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bambermycins provided by No. 057926 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Bambermycins, 1 gram plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent).

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 days before slaughter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bambermycins provided by No. 057926 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(viii) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent).

(a) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; zoalene as provided by No. 025700 in § 510.600(c) of this chapter.

(ix) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125

percent) plus roxarsone, 22.7 grams (0.0025 percent).

(a) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; feed as sole source of organic arsenic; withdraw 5 days before slaughter; zoalene as provided by No. 025700, roxarsone as provided by No. 046573 in §510.600(c) of this chapter.

(x) [Reserved]

(xi) *Amount per ton.* Bambermycins 1 to 2 grams, plus roxarsone 45.4 grams, and salinomycin 40 to 60 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. tenella*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone; and for improved feed efficiency.

(b) *Limitations.* For broiler chickens only; do not feed to laying chickens; feed continuously as sole ration; as sole source or organic arsenic; withdraw 5 days before slaughter; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses; as roxarsone provided by No. 011526 or 046573 in §510.600(c) of this chapter; as salinomycin sodium biomass provided by Nos. 046573 and 048164 in §510.600(c) of this chapter.

(xii) *Amount per ton.* Bambermycins 1 to 3 grams, plus salinomycin 40 to 60 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and improved feed efficiency.

(b) *Limitations.* For broiler chickens only; Do not feed to laying chickens; feed continuously as sole ration; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses; as salinomycin sodium biomass provided by Nos. 046573 and 057926 in §510.600(c) of this chapter.

(xiii) *Amount per ton.* Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams (0.0025 to 0.005 percent).

(a) *Indications for use.* For increased rate of weight gain; as an aid in prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* See paragraph (b)(1)(vii)(b) of this section.

(xiv) *Amount per ton.* Bambermycins 1 to 2 grams, plus lasalocid 68 to 113 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency in broiler chickens.

(b) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Lasalocid as provided by No. 046573 in §510.600(c) of this chapter.

(2) *Growing-finishing swine.* It is used as follows:

(i) *Amount per ton.* 2 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration.

(ii) *Amount per ton.* 2 to 4 grams.

(a) *Indications for use.* For increased rate of weight gain.

(b) *Limitations.* Feed continuously as sole ration.

(3) *Growing turkeys.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

(a) *Indications for use.* For improved feed efficiency.

(b) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* 2 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration.

(iii) *Amount per ton.* Bambermycins, 1 to 4 grams plus amprolium, 113.5 grams (.0125 percent).

(a) *Indications for use.* For prevention of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as the sole source of amprolium; amprolium as provided by No. 050604 in §510.600(c) of this chapter.

(iv) *Amount per ton.* Bambermycins, 1 or 4 grams plus carbarsone, 227 grams (0.025 percent).

(a) *Indications for use.* For improved feed efficiency (1 gram per ton) or increased rate of weight gain (4 grams per ton); as an aid in the prevention of blackhead.

(b) *Limitations.* Feed continuously 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of organic arsenic; carbarsone by 046573 in § 510.600(c) of this chapter.

(4) *Cattle*—(i) *Amount per ton.* 1 to 4 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C medicated feed at a rate of 10 to 20 milligrams of bambermycins per head per

day. Liquid Type B feeds containing bambermycins may be used in the preparation of dry complete ration Type C feeds.

(ii) *Amount per ton.* 2 to 40 grams.

(a) *Indications for use.* For increased rate of weight gain.

(b) *Limitations.* Feed continuously to pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) at a rate of 10 to 40 milligrams of bambermycins per head per day in at least 1 pound and not more than 10 pounds of Type C medicated feed. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(iii) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) as follows:

(a) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6-01-080	42.50
Sodium chloride (salt)	6-04-152	20.10
Calcium carbonate (38% calcium)	6-01-069	15.24
Corn distillers dried grains w/solubles	5-28-236	9.57
Magnesium oxide	6-02-756	5.15
Vitamin and trace mineral premix *	3.72
Mineral oil	1.00
Yeast (primary dehydrated yeast)	7-05-533	0.75
Bambermycins Type A article (10 g/lb)	0.60
Iron oxide	6-02-431	0.50
Magnesium sulfate (67%)	6-02-758	0.32
Selenium premix (270 mg/lb) *	0.21
Copper sulfate	6-01-720	0.18
Potassium sulfate (0.33%)	6-06-098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(b) *Amount per ton.* 120 grams.

(c) *Indications for use.* For increased rate of weight gain.

(d) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Each use of this free-choice Type C medicated feed must be the subject of an approved Form FDA 1900 as required by 21 CFR 510.455.

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) as follows:

(a) *Amount.* Feed continuously to provide 10 to 40 milligrams of bambermycins per head per day.

(b) *Indications for use.* For increased rate of weight gain.

(c) *Limitations.* Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455. Daily bambermycins intakes in

excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(5) Bambermycins may be used in combination with:

- (i) Diclazuril as in § 558.198.
- (ii) Halofuginone as in § 558.265.
- (iii) Monensin as in § 558.355.
- (iv) Narasin alone or with nicarbazin or roxarsone as in § 558.363.
- (v) Nicarbazin as in § 558.366.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.95, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.105 [Reserved]

§ 558.115 Carbadox.

(a) *Approvals.* Type A medicated articles: 2.2 percent (10 grams per pound) to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.100 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106 percent).

(i) *Indications for use.* For control of swine dysentery (vibronic dysentery,

bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in complete feeds containing less than 15 percent crude protein.

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 45164, Oct. 1, 1975; 40 FR 57798, Dec. 12, 1975; 42 FR 761, Jan. 4, 1977; 51 FR 7396, Mar. 3, 1986; 63 FR 59216, Nov. 3, 1998; 66 FR 47963, Sept. 17, 2001; 69 FR 51173, Aug. 18, 2004]

§ 558.120 Carbarsone (not U.S.P.).

(a) *Approvals.* Type A medicated articles: (1) 37.5 percent to 046573 in § 510.600(c) of this chapter.

(2) 25 percent carbarsone and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) It is used for turkeys as follows:

(i) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent).

(a) *Indications for use.* As an aid in the prevention of blackhead.